

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 02177.0009P1	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/US2008/011393	International filing date ( <i>day/month/year</i> ) 02 October 2008 (02.10.2008)	Priority date ( <i>day/month/year</i> ) 03 October 2007 (03.10.2007)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant BYOCOAT ENTERPRISES, INC.			

- This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
- This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

- This report contains indications relating to the following items:

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Box No. I   | Basis of the report   |
| <input type="checkbox"/> Box No. II             | Priority  |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV             | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V   | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI             | Certain documents cited   |
| <input type="checkbox"/> Box No. VII            | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII           | Certain observations on the international application   |

- The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Date of issuance of this report 07 April 2010 (07.04.2010)
	Authorized officer  Philippe Becamel  e-mail: pt12.pct@wipo.int

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:  
BALLARD SPAHR ANDREWS & INGERSOLL,  
LLP  
SUITE 1000, 999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

Date of mailing  
(day/month/year)

18 DEC 2008

Applicant's or agent's file reference  
02177.0009P1

### FOR FURTHER ACTION

See paragraph 2 below

International application No.  
PCT/US 08/11393

International filing date (day/month/year)  
02 October 2008 (02.10.2008)

Priority date (day/month/year)  
03 October 2007 (03.10.2007)

International Patent Classification (IPC) or both national classification and IPC  
IPC(B) - A01N 43/78 (2008.04)  
USPC - 514/366

Applicant BYCOAT ENTERPRISES, INC.

### 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-3201

Date of completion of this opinion

04 December 2008 (04.12.2008)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300  
PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/11393

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:  
☒ the international application in the language in which it was filed.  
☐ a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a)).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
  - a. type of material:  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ on paper  
☐ in electronic form
  - c. time of filing/furnishing  
☐ contained in the international application as filed  
☐ filed together with the international application in electronic form  
☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/11393

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 4-38 and 50-51

because: these claims are improper multiple dependent claims.

☐ the said international application, or the said claims Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international search (specify):

☒ the description, claims or drawings (indicate particular elements below) or said claims Nos. 4-38 and 50-51 are so unclear that no meaningful opinion could be formed (specify):

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed (specify):

☒ no international search report has been established for said claims Nos. 4-38 and 50-51

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 08/11393

**Box No. V Reasoned statement under Rule 43b6.1(a)(i) with regard to novelty, inventive step or industrial applicability:  
citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	1-3, 39-49	YES
	Claims	none	NO
Inventive step (IS)	Claims	none	YES
	Claims	1-3, 39-49	NO
Industrial applicability (IA)	Claims	none	YES
	Claims	1-3, 39-49	NO

**2. Citations and explanations:**

Claims 1-3 and 39-49 lack an inventive step under PCT Article 33(3) as being obvious over WO 2007/030104 A1 to BURWELL et al (hereinafter "Burwell") in view of US 7,109,241 B1 to RICHTER et al (hereinafter "Richter") and in further view of US 2003/0113384 A1 to FREDELL et al (hereinafter "Fredell").

As to Claim 1, Burwell discloses a biocidal composition for use in a mammal comprising a) from about 0.05% to about 8% by weight of biocidal system (pg 11, in 17-19; pg 12, in 14-16; pg 15, in 15-21), comprising:

- i) greater than 20% by weight of a primary biocide (pg 15, in 22-27) and
  - ii) a preservative component (pg 29, in 24-25);
  - b) a surfactant (pg 29, in 28);
  - c) an emollient system comprising:
    - i) penetrating agent (pg 29, in 14-23; "propylene glycol") and
    - ii) emollient base (pg 29, in 14-23; "polyol") and
    - d) a thickener (pg 29, in 29; "acacia") and
    - e) the balance an aqueous based carrier (Pg 34, in 23-33; "water").
- Burwell does not disclose the amount of each carrier or excipient in the composition and that the biocidal composition can be used to improve teat and udder hygiene.

Richter discloses a biocidal composition for improving teat hygiene in a mammal comprising from about 1 to 3 % by weight of an emollient system comprising at least 50% of an emollient base (Col 4, in 3-12; Col 4, in 23-25; Col 4, in 28-33; Col 6, in 18-27; Col 10, in 4-11). Richter does not disclose the amount of other components in the biocidal composition.

Fredell discloses a composition for improving teat hygiene in a mammal comprising from about 1% (para [0041]; [0044]; pg 6, Table 1; "Pluronic") and about 0.1 to 1% of thickening agent (para [0039]; pg 6, table 1; "Kelzan")

It would have been obvious to the combining the teachings of Burwell, Richter and Fredell, an antimicrobial pharmaceutical composition for the improvement of hygiene in a mammal can be designed with the components as disclosed by Burwell in amounts that can produce effective antimicrobial activity depending on the potency of the active ingredient and together with a large amount of emollients will allow for a composition that will retain moisture in the skin of the mammal, and the remaining components in smaller amounts, would be enough to maintain the stability and increase the permeability and penetration of the composition through the skin.

As to Claim 2, Burwell discloses the composition according to claim 1, wherein the primary biocide is a quaternary ammonium salt comprising at least one aryl or heteroaryl unit (pg 30, in 14-21).

As to Claim 3, Burwell discloses the composition according to claims 1-3, wherein the primary biocide is chosen from alkyl-dialkyl-benzyl ammonium salts and alkyl heteroaryl ammonium salts (pg 30, in 14-26; pg 34, in 23-33).

As to Claim 39, it is obvious for reasons as set forth in claim 1 and further Fredell discloses the surfactant as one with HLB from about 10 to 20 (para [0041]; "polyoxy-ethylene polymer")

As to Claim 40, it is obvious for reasons as set forth in claim 1 and further, Burwell discloses the primary biocide is cetyl pyridinium chloride (pg 34, in 23-33; pg 35, in 2), the preservative is urea. Fredell further discloses the preservative as urea (para [0047]), the surfactant as polyoxyethylene polymer (para [0041]), an emollient system comprising propylene glycol and glycerol (para [0041]; [0046]) and hydroxycellulose as a thickening agent (para [0038]).

As to Claim 41, it is obvious for reasons as set forth in claim 1 and further Fredell discloses the surfactant as an anionic or nonionic surfactant (para [0040]) and a thickening agent as xanthum gum or locust bean gum (para [0038]).

As to Claim 42, it is obvious for reasons as set forth in claim 1 and further Fredell discloses the a method of treating mastitis in an infected animal (para [0009]; [0017]) comprising a nonionic surfactant (para [0040]).

\*\*\*\*\*CONTINUED IN SUPPLEMENTAL BOX\*\*\*\*\*

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/11393

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:  
BOX V.2

As to Claim 43, it is obvious for reasons as set forth in claims 1 and 42.

As to Claim 44, it is obvious for reasons as set forth in claims 1 and 40 and further Burwell discloses a biocidal composition comprising cetyl ammonium chloride (pg 33, ln 6-20).

As to Claim 45, it is obvious for reasons as set forth in claims 1 and 39 and further Fredell discloses a method of preventing mastitis in an infected animal exposed to a pathogen comprising a biocidal composition (para [0009]; [0015]; [0017]).

As to Claims 46-49, they are obvious for reasons as set forth in claims 1, 40, 41 and 45.

Claims 1-3 and 39-49 have industrial applicability as defined by PCT Article 33(4), because the subject matter can be made or used in industry.